DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration						Form Approved: OMB No. 0910-0806 Expiration Date: January 31, 2022		
	Drug N	Votific	ation	1			See PRA Statement on page 2.	
	Refer to instruct	ion sheet	(Form	FDA	3911 Supplement) fo	r mor	re information.	
Type of Report (Sei	lect one):	Initial Notif	fication		Follow-Up Notific	cation	Request for Termination	on
	rovide this number, ass on above; see instruction		FDA, if y	ou se	elected Follow-up Notifi	ication	or	
 Date of Initial Notific (mm/dd/yyyy) 03/25/2021 	n/dd/yyyy) Illegitimate (mm/dd/yyyy) from list			lassification of Notification (Select n list) audulent Transaction	f •			
Description of Produ	ıct							
6. Name of Product as								
Biktarvy 30CT								
7. Primary Ingredients BICTEGRAVIR, I	(s) (if known) EMTRICITABIN, TEN	IOFOVIR	ALAFE	ENEM	IIDE FUMARATE			
8. Drug Use (Select fr	om list)			9. Di	rug Description (Select	from I	list)	
Human Use			•	Fi	inished Prescription Dr	ug	•	*
10. Strength of Drug					11. Dosage Form (Sele	ect fro	m list)	
50MG/200MG/251	MG				Tablet			•
12. Quantity of Drug (Number and Unit)		13. ND	C Nu	mber (if applicable)	14. S	erial Number (if applicable)	
3 bottles			6195	8-250	01-01			
15. Lot Number(s)								
CCXKVA, CCZCI	FA, CDFYCA							
16. Expiration Date(s)								
17. For Notification: D	escription of Event/Issu	ie						
See additional page	e							
							Add Page for It	em 17
18. For Request for Te	ermination of Notification	n: Descrip	tion of w	why n	otification is no longer	neces	sary	
							Add Page for It	em 18
19. If you have submit	ted information to FDA	through a	n alterna	ative	mechanism, check all t	hat ap		
BPDR	MedWatch 350		_	one				
☐ FAR	MedWatch 350		_		Specify):			
_	_						PSC Publishing Services (301)	143-6740 EF
- CKM FDA 3311 (2/1	9 – PREVIOUS VERSIO		L12)	rage	e 1 of 2		For Fernand our loss (201)	and the

GOVERNMENT EXHIBIT 634A 1:24-cr-20255-WPD

Company/Facility Information									
20.	20. Company Name & Address								
	Name								
	Safe Chain Solutions								
	Address 1 (Street address, P.O. box, etc.)								
	822 Chesapeake Drive								
	Address 2 (Apartment, suite, unit, building, floor, etc.)								
	City	State/Province	e/Region						
	Cambridge MD								
	Country			ZIP or Postal Code					
	United States			21613					
21.	1. Company Category (Select from list)								
	Wholesale Distributor				•				
22.	Unique Facility Identifier (of company named in #20)								
	025667294								
23.	Contact Information (Note: For the telephone, you may enter the	number of eith	her the co	ntact person or of the company named in #20.,)				
	Name			ne Number (Include area code)					
	Charles Boyd		855-43	37-5727					
	Email Address								
	Charlesb@safechain.com								
	SUBM	IIT BY EMAIL							
	A willfully false statement is a criminal offe	nse, pursua	nt to U.	S. Code, title 18, section 1001.					

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration Office of Operations Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

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Case 1:24-cr-20255-WPD Document 237-14 Entered on FLSD Docket 11/07/2025 Page 3 of 11

OFFICIAL UNITED STATES FOOD AND DRUG ADMINISTRATION (US FDA) DOCUMENTS; DO NOT DISCLOSE WITHOUT WRITTEN PERMISSION OF US FDA OR INFORMATION OWNER

CONTINUATION PAGE FOR ITEM 17 - For Notification: Description of event/issue

In the space below, please continue the description of the event/issue.

Safe Chain received three complaints from pharmacies regarding Biktarvy. In one of the cases, the bottle was identified by the dispensing pharmacist to contain another Gilead product Stribild. Right away Gilead QC Department asked us if we purchase Stribild. We were informed from our supplier GenTek via email to "Please go ahead and destroy the product. That's a mixed batch error on our AD". We asked that specific question of Gilead. After promptly filing a complaint with Gilead's QC Dept and providing photos, we sent the product to Gilead. Safe Chain heard nothing back until yesterday.

In one of the cases, we asked Gilead if they had made a DSCSA "determination" and they indicated they have not reported to the FDA because they have merely commented but not made a DSCSA "determination." Gilead has also refused to let us know if there have been any other reports with other wholesalers.

For each complaint, Safe Chain declined these specific lots from any vendors, quarantined the specific lot, and contacted the manufacturer and immediately filing a product quality complaint with the QC Complaints Dept of the manufacturer, Gilead Sciences, Inc. (Lot CCZCFA- Gilead complaint # PR# 213279) (Lot CDFYCA- Reported to Gilead- Complaint # PR196084) (Lot CCXKVA)-Reported to Gilead- Not assigned a complaint number by Gilead's QC Dept but we have the paper trail). Where product was returned to Safe Chain, we quarantined the product, until Gilead was able to coordinate the return to their facility. We provided photos at their request. Gilead was also provided with copies of the T3 data and Safe Chain awaited "DSCSA determinations" from Gilead which were never forthcoming. Safe Chain also asked Gilead to report this to FDA if they made a determination the product was illegitimate. On March 24, 2021 our counsel at Frier Levitt, LLC received a letter from Gilead's counsel (not their QC Department) indicating what we believe to be a "determination" regarding these 3 product complaints that Safe Chain reported to Gilead. Gilead has stated that that the T3 data was false inasmuch as Gilead never sold the lots in question to their Authorized Distributer Drogueria Betances (Betances). The T3 we received from our supplier indicates this authorized distributor sold the product to GenTek who in turn sold the product to Safe Chain. That is, GenTek has indicated they purchased from Betances and this is reflected in the T3. Since the "determination" does not indicate that Gilead has or intends to report suspect product determination to the FDA, Safe Chain is doing so. Please advise us what the next steps are.

Safe Chain Solutions LLC Cambridge, MD 21613-9408 FEI: 3009729473 04/11/15 - 05/10/21 MDD, CMP Exhibit CMP-19 << Page 3 of 3>>

Food and Drug Administration						Form Approved: OMB No. 0910-0 Expiration Date: January 31, 2023		
Drug Notification See PRA Sta						See PRA Statement on page 2.		
	Refer to instruct	tion sheet	(Form F	DA 3911 Supplement)	for mo	re information.		
1. Type of Report (Select one):								
	Provide this number, as tion above; see instructi		DA, if yo	u selected Follow-up No	tificatio	n or		
					Classification of Notification (Select			
03/27/2021	(dd/yyyy) Illegitimate (mm/dd/yyyy) from list) 3/27/2021 Unfit for Distribution					-	¥	
						mil for Distribution		
escription of Product a	as It Appears on Label							
BIKTARVY 30C								
. Primary Ingredients								
		NOFOVIR A	ALAFE	NEMIDE FUMARATE				
. Drug Use (Select fi	from list)		8	Drug Description (Sele		list)		
Human Use			~	Finished Prescription	Drug		-	
0. Strength of Drug				11. Dosage Form (S	elect fro	om list)		
50MG/200MG/25	MG			Tablet			7	
2. Quantity of Drug	(Number and Unit)		13. NDC	Number (if applicable)	14. 9	Serial Number (if applicable)		
2 bottles			61958	-2501-01				
5. Lot Number(s)								
CDSFFA, 19BIC0	038A							
CDSFFA, 19BIC0 6. Expiration Date(s								
6. Expiration Date(s		038A EXP:	: 3/2021					
Expiration Date(s Lot CDSFFA EXF For Notification: D	P: 12/2022 Lot 19BIC Description of Event/Iss	ue						
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Company/Facility Information							
20. Company Name & Address							
Name							
Safe Chain Solutions							
Address 1 (Street address, P.O. box, etc.)							
822 Chesapeake Drive	822 Chesapeake Drive						
Address 2 (Apartment, suite, unit, building, floor, etc.)							
City	State/Province/Region	1					
Cambridge	MD						
Country	•	ZIP or Postal Code					
United States		21613					
21. Company Category (Select from list)		-					
Wholesale Distributor							
22. Unique Facility Identifier (of company named in #20)							
025667294							
23. Contact Information (Note: For the telephone, you may enter the	e number of either the c	ontact person or of the company named in #20.)					
Name	Telepho	one Number (Include area code)					
Charles Boyd	855-4	855-437-5727 X1001					
Email Address	'						
charlesb@safechain.com							
SUBN	MIT BY EMAIL						

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DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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FORM FDA 3911 (2/19 - PREVIOUS VERSION OBSOLETE) Page 2 of 2

Food and Drug Adn Drug Notific	Form Approved: OMB No. 0910-0806 Expiration Date: January 31, 2022 See PRA Statement on page 2.							
Refer to instruction shee	et (Form	FD	A 3911 Supplement) fo	r moi	re information.			
1. Type of Report (Select one):								
Incident Number (Provide this number, assigned by Request for Termination above; see instructions.) 45		you	selected Follow-up Notifi	ication	or			
/dd/yyyy) Illegitimate (mm/dd/yyyy) from list)				lassification of Notification (Select n list) affit for Distribution				
Description of Product		_						
6. Name of Product as It Appears on Label								
BIKTARVY 30CT								
7. Primary Ingredients(s) (if known) BICTEGRAVIR, EMTRICITABIN, TENOFOVII	R ALAFE	ENE	MIDE FUMARATE					
8. Drug Use (Select from list)		9.1	Drug Description (Select	from I	list)			
Human Use	•		Finished Prescription Dr	ug	•			
10. Strength of Drug 50MG/200MG/25MG			11. Dosage Form (Sele Tablet	ect fro	m list)			
12. Quantity of Drug (Number and Unit)	13 ND	C N	lumber (if applicable)	14 S	erial Number (if applicable)			
				14. 0	enanvanice (n approable)			
	2 bottles 61958-2501-01							
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CDSFFA, 19BIC038A 16. Expiration Date(s)	rp. 3/2021	1	'					
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П	Name						
	Safe Chain Soltions						
	Address 1 (Street address, P.O. box, etc.)						
	822 Chesapeake Drive						
	Address 2 (Apartment, suite, unit, building, floor, et	tc.)					
	City		State/Province	e/Region			
	Cambridge		MD				
	Country				ZIP or Postal Code		
	United States				21613		
1.	Company Category (Select from list)						
	Wholesale Distributor					•	
2.	Unique Facility Identifier (of company named in #	20)					
	025667294						
3.	Contact Information (Note: For the telephone, you	may enter th	e number of eit	her the co	ntact person or of the company named in #20	2.)	
	Name			Telephor	ne Number (Include area code)		
	Charles Boyd			855-43	37-5727		
	Email Address						
	charlesb@safechain.com						
			ense, parsac	int to o.	S. Code, title 18, section 1001.		
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	This section applies only *DO NOT SEND YOUR COMPLE	to requirem	ents of the Pa	perwork	Reduction Act of 1995.		
		to requirem ETED FORI formation is ting data so n. Send corr	ents of the Pa M TO THE PR s estimated to ources, gather nments regard	perwork A STAFI average and main	Reduction Act of 1995. F EMAIL ADDRESS BELOW.* 1 hour per response, including the nation the data needed and complete urden estimate or any other aspect		
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DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration Drug Notification						Form Approved: OMB No. 091 Expiration Date: January 31, 2 See PRA Statement on page	2022
Drug i	Drug Notification						
Refer to instruction sheet (Form FDA 3911 Supplement) for more information.							
1. Type of Report (Select one): 🔲 Initial Notification 🔲 Follow-Up Notification 🔲 Request for Termination							
Incident Number (Provide this number, as Request for Termination above; see instruction		FDA, if	you s	selected Follow-up Notifi	ication	or	
mm/dd/yyyy) Illegitimate (mm/dd/yyyy) from				lassification of Notification (Sele hist) fit for Distribution	ct		
Description of Product							
6. Name of Product as It Appears on Label Biktarvy 30CT							
7. Primary Ingredients(s) (if known) BICTEGRAVIR, EMTRICITABIN, TEN	NOFOVIR	ALAFI	ENE:	MIDE FUMARATE			
8. Drug Use (Select from list)			9. [Orug Description (Select	from l	ist)	
Human Use		~	I	Finished Prescription Dr	ug		-
10. Strength of Drug				11. Dosage Form (Sele	ect fron	m list)	
50MG/200MG/25MG				Tablet			▼
12. Quantity of Drug (Number and Unit)		13. NE	C N	umber (if applicable)	14. Se	erial Number (if applicable)	
l bottle		6195	8-25	501-01			
15. Lot Number(s)							
6400501A							
16. Expiration Date(s)							
17. For Notification: Description of Event/Iss	ue						
Safe Chain Solutions compliance departs had a complaint about one bottle of BIKT Garden Grove, CA 92843, had a patient s they had preciously been prescribed this a 6400501A to this patient. Safe Chain has await further instruction. Safe Chain has	FARVY. T state that the medication asked the	he custo nere was n. The P pharma	omer s Stri IC, T	, Global Express Pharm bild in their bottle of Bl Tuan, stated that he disp o return the bottle to us,	acy lo KTAR ensed : so that	cated at 10596 Garden Grove B RVY. The patient recognized th a closed bottle of BIKTARVY t we may quarantine the produc	BLVD, e pill as lot
						Add Page for	Item 17
18. For Request for Termination of Notification	on: Descrip	otion of	why	notification is no longer	necess	sary	
						Add Page for	Item 18
19. If you have submitted information to FDA	through a	n altern	ative	mechanism, check all t	hat ap	ply.	
☐ BPDR ☐ MedWatch 350	00	■ N	lone				
FAR MedWatch 350	00A		ther	(Specify):			
FORM FDA 3911 (2/19 – PREVIOUS VERSION	ON OBSOL	.ETE)	Pag	ge 1 of 2		PSC Publishing Services (30	I)443-6740 EF

Company/Facility Information								
20. Company Name & Address								
Name								
Safe Chain Solutions								
Address 1 (Street address, P.O. box, etc.)								
822 Chesapeake Drive								
Address 2 (Apartment, suite, unit, building, floor, etc.)								
City	State/Province/Region							
Cambridge	MD							
Country	•	ZIP or Postal Code						
United States		21613						
21. Company Category (Select from list)								
Wholesale Distributor		•						
22. Unique Facility Identifier (of company named in #20)								
025667294								
23. Contact Information (Note: For the telephone, you may enter the	e number of either the co	ntact person or of the company named in #20.)						
Name		ne Number (Include area code)						
Charles Boyd	855-437-5727 X1001							
Email Address								
charlesboyd@safechain.com								
SUBN	IIT BY EMAIL							
A willfully false statement is a criminal offe	ense, pursuant to U.	S. Code, title 18, section 1001.						

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services Food and Drug Administration Office of Operations Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

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FORM FDA 3911 (2/19 – PREVIOUS VERSION OBSOLETE) Page 2 of 2

DEPARTMENT OF HEALTH AND HUMAN SERVICES Food and Drug Administration						Form Approved: OMB No. 0910- Expiration Date: January 31, 202	
Drug Notification See PRA Statement on page 2.							
Refer to instru	uction sheet	t (Form	FDA	A 3911 Supplement) fo	r mor	e information.	
1. Type of Report (Select one):							n
Incident Number (Provide this number, Request for Termination above; see instru		FDA, if y	ou :	selected Follow-up Notif	ication	or	
3. Date of Initial Notification to FDA				termined Product Was	1	lassification of Notification (Select	
(mm/dd/yyyy) 04/07/2021	Illegitimat 04/06/2	•	id/y	yyy)	from	i list) audulent Transaction	▼
Description of Product	0 1/ 00/2	.021				addition Timberion	
6. Name of Product as It Appears on Labe	al						
BIKTARVY, COMPLERA, GENVO		EY, TRU	JVA	DA			
7. Primary Ingredients(s) (if known)	-						
9. Deve Lies (Salast from Est)			0.1	Dava Dasseistica (Salast	f 1	C_40	
8. Drug Use (Select from list) Human Use		•	l	Drug Description (Select Finished Prescription Di		istj	▼
						(T-4)	
10. Strength of Drug VARIES				11. Dosage Form (Sele Tablet	ect iron	m iist)	▼
12. Quantity of Drug (Number and Unit)		13 ND	C N	umber (if applicable)	14 5	erial Number (if applicable)	
177 bottles		13. ND	CIV	итьег (іг арріісавіе)	14. 3	eriai Number (ii applicable)	
15. Lot Number(s)							
multiple							
16. Expiration Date(s)							
multiple							
17. For Notification: Description of Event/I	ssue						
Safe Chain Solutions placed an order to 10333 Harwin Dr, Ste 263, Houston, T Sciences. Upon trying to verify the T3 inconsistent with their records. They h Gilead know that they did not sell thes product.	X for approx information ad no record	cimately provided of sellin	177 d to g th	7 bottles of various HIV us, Gilead informed Saf ie products to Amerisou	medic e Chai rce Ber	ations all manufactured by Gilead in that that T3 information was rgen, and Amerisource Bergen let	e
18. For Request for Termination of Notific	ation: Descrip	ption of v	why	notification is no longer	necess	sary	
						Add Page for Ite	em 18
19. If you have submitted information to F	-	_			hat ap	ply.	
BPDR MedWatch 3		_ N	one				
FAR MedWatch 3	3500A	□ o	ther	(Specify):			
FORM FDA 3911 (2/19 - PREVIOUS VER	SION OBSOI	LETE)	Pag	ge 1 of 2		PSC Publishing Services (301) 44	13-6740 EF

Company/Facility Information	
20. Company Name & Address	
Name	
Safe Chain Solutions	
Address 1 (Street address, P.O. box, etc.)	
822 Chesapeake Drive	
Address 2 (Apartment, suite, unit, building, floor, etc.)	
City	State/Province/Region
Cambridge	MD
Country	ZIP or Postal Code
United States	21613
21. Company Category (Select from list)	
Wholesale Distributor	•
22. Unique Facility Identifier (of company named in #20)	
025667294	
23. Contact Information (Note: For the telephone, you may enter the	he number of either the contact person or of the company named in #20.)
Name	Telephone Number (Include area code)
Charles Boyd	855/437/5727 X 1001
Email Address	·
charlesb@safechain.com	
SUB	MIT BY EMAIL
A willfully false statement is a criminal off	fense, pursuant to U.S. Code, title 18, section 1001.

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FORM FDA 3911 (2/19 – PREVIOUS VERSION OBSOLETE) Page 2 of 2